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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,342

12/30/2003

Mark A. Dombroski

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06/14/2005

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EXAMINER

PAVIGLIANITI, ANTHONY JOSEPH

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/748,342

Applicant(s)

DOMBROSKI ET AL.

Examiner

Anthony J. Paviglianiti

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 is/~~are~~ *allowable over the prior art of record. ATJ*
- 6) ☒ Claim(s) 1-3 and 6-9 is/are rejected.
- 7) ☒ Claim(s) 1-9 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

**Claims 1 – 12** are currently pending in the application. Restriction was required by the examiner. Applicant elected **Group I (Claims 1 – 11)**. **Claim 12** was withdrawn from further consideration as being drawn to a non-elected invention, pursuant to 37 C.F.R. §1.142(b).

**Priority**

This application claims benefit of U.S. Provisional Application No. 60/437,228, with filing date December 31, 2002.

**Information Disclosure Statement**

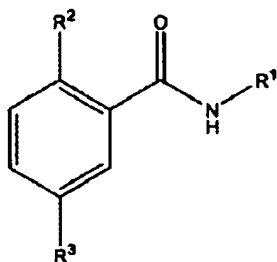
There was no Information Disclosure Statement of record for this application for consideration by the examiner.

**Specification**

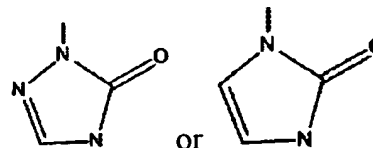
Please fill in the blank U.S. Serial Number on page 1, line 21 of the Specification.

**Election/Restrictions**

Applicant's "Response to Restriction Requirement," dated May 5, 2005, is hereby acknowledged. In that response, **Applicant elected, without traverse, the subject matter of Group I (Claims 1 – 11)**, drawn to compounds and compositions of formula (I)

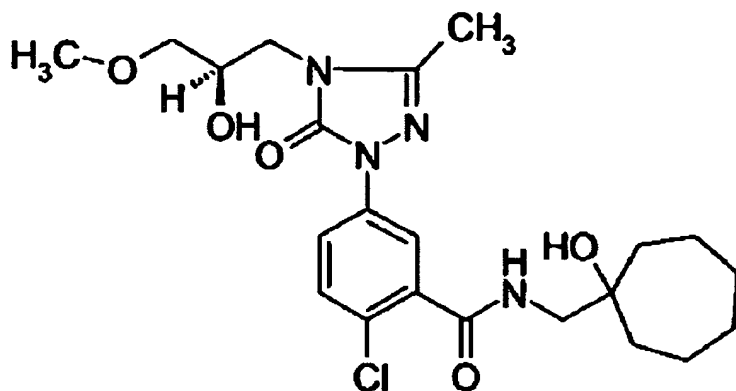


(I), where the primary substituent,  $R^3$ , is



Art Unit: 1626

Applicant further elected a specific embodiment of the elected invention for purposes of examination: "Example 12" (Specification at p. 68, lines 3 – 10), which is 2-Chloro-N-(1-hydroxy-cycloheptylmethyl)-5-[4-(2-hydroxy-3-methoxy-propyl)-3-methyl-5-oxo-4,5-dihydro-[1,2,4]triazol-1-yl]-benzamide, with chemical structure:

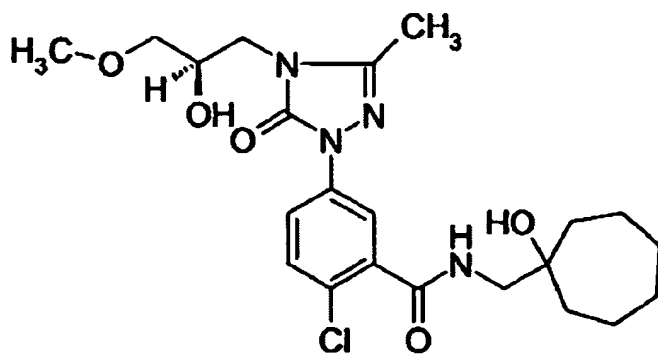


Accordingly, **Claim 12** was withdrawn from further consideration as being drawn to a non-elected invention, pursuant to 37 C.F.R. §1.142(b).

### **Scope of Prior Art Searched**

#### **1) Elected compound**

The compound 2-Chloro-N-(1-hydroxy-cycloheptylmethyl)-5-[4-(2-hydroxy-3-methoxy-propyl)-3-methyl-5-oxo-4,5-dihydro-[1,2,4]triazol-1-yl]-benzamide, with structure:

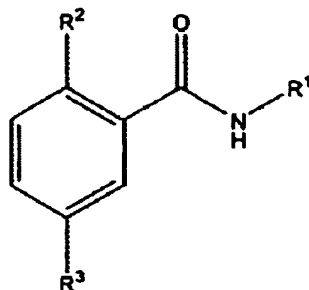


was searched, and found to be free of the prior art.

Art Unit: 1626

2) *Expansion of search of the prior art beyond the elected compound*

The search of the prior art was broadened by a series of expanding searches of the genus



structure (I)

(i), with the final (cumulative) areas of the art

searched encompassing the following values for **R<sup>1</sup>**, **R<sup>2</sup>**, and **R<sup>3</sup>** (and **R<sup>4</sup>**, **R<sup>5</sup>**, **R<sup>6</sup>**, and **R<sup>7</sup>**, where applicable) as shown:

**R<sup>1</sup>** is: (C<sub>1</sub>-C<sub>6</sub>) alkyl;

optionally substituted by (C<sub>3</sub> - C<sub>10</sub>) cycloalkyl; (C<sub>6</sub> - C<sub>10</sub>) aryl;

where each group above is optionally substituted by one to three of the following groups: hydroxy; halogen; -CN; (C<sub>1</sub>-C<sub>6</sub>) alkyl; HO(C<sub>1</sub>-C<sub>6</sub>) alkyl-; (C<sub>1</sub>-C<sub>6</sub>) alkyl-NHC(O)-; NH<sub>2</sub>(C=O)-; (C<sub>1</sub>-C<sub>6</sub>) alkoxy; or (C<sub>3</sub>-C<sub>10</sub>) cycloalkyl;

wherein the (C<sub>3</sub>-C<sub>10</sub>) cycloalkyl group is optionally substituted by one or more halogens or (C<sub>1</sub>-C<sub>6</sub>) alkyl groups; *[note: does not include (C<sub>1</sub>-C<sub>10</sub>) heterocyclyl or (C<sub>1</sub>-C<sub>10</sub>) heteroaryl groups];*

**R<sup>2</sup>** is: hydrogen;

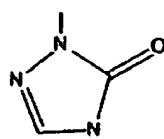
halogen;

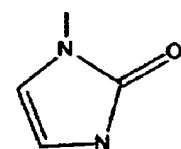
-CN; and

(C<sub>1</sub>-C<sub>6</sub>) alkyl; wherein the (C<sub>1</sub>-C<sub>6</sub>) alkyl is optionally substituted by one to three groups independently selected from halo, hydroxy, amino, -CN, (C<sub>1</sub>-C<sub>6</sub>) alkyl,

Art Unit: 1626

(C<sub>1</sub>-C<sub>6</sub>) alkoxy; -CF<sub>3</sub>, CF<sub>3</sub>O-, (C<sub>1</sub>-C<sub>6</sub>) alkyl-NH-, [(C<sub>1</sub>-C<sub>6</sub>) alkyl]<sub>2</sub>-N-, (C<sub>1</sub>-C<sub>6</sub>) alkyl-S-, (C<sub>1</sub>-C<sub>6</sub>) alkyl-(S=O)-, (C<sub>1</sub>-C<sub>6</sub>)alkyl-(SO<sub>2</sub>)-, (C<sub>1</sub>-C<sub>6</sub>) alkyl-O-(C=O)-, formyl, (C<sub>1</sub>-C<sub>6</sub>) alkyl-(C=O)-, and (C<sub>3</sub>-C<sub>6</sub>) cycloalkyl;

**R<sup>3</sup>** is: (1) 5-oxo-4,5-dihydro-[1,2,4]-triazol-1-yl group,  ; *or*

(2) 2-oxo-1,3-diazole (i.e., imidazol-2-one) group,  ;

either of which may be optionally be substituted by variables **R<sup>4</sup>** and **R<sup>7</sup>** (if a triazole ring) or **R<sup>4</sup>**, **R<sup>5</sup>**, and **R<sup>7</sup>** (if an imidazole ring), as described below;

**R<sup>4</sup>** is: hydrogen;

halo;

hydroxy;

-CN;

HO-(C<sub>1</sub>-C<sub>6</sub>) alkyl -; and

(C<sub>1</sub>-C<sub>6</sub>) alkyl,

wherein the (C<sub>1</sub>-C<sub>6</sub>) alkyl group is optionally substituted by one to three fluoro, (C<sub>1</sub>-C<sub>6</sub>) alkoxy optionally substituted with one to three fluoro, HO<sub>2</sub>C-, (C<sub>1</sub>-C<sub>6</sub>) alkyl-O-(C=O)-, R<sup>6</sup>R<sup>8</sup>N(O<sub>2</sub>S)-, (C<sub>1</sub>-C<sub>6</sub>)alkyl-(O<sub>2</sub>S)-NH-, (C<sub>1</sub>-C<sub>6</sub>)alkyl-O<sub>2</sub>S-[(C<sub>1</sub>-C<sub>6</sub>)alkyl-N]-, R<sup>6</sup>R<sup>8</sup>N(C=O)-, R<sup>6</sup>R<sup>8</sup>N(CH<sub>2</sub>)<sub>m</sub>-, (C<sub>6</sub>-C<sub>10</sub>) aryl; (C<sub>6</sub>-C<sub>10</sub>) aryl-O-, (C<sub>3</sub>-C<sub>8</sub>) cycloalkyl, and (C<sub>3</sub>-C<sub>8</sub>) cycloalkyl-O-; [note: does not include (C<sub>1</sub>-C<sub>10</sub>) heterocyclyl or (C<sub>1</sub>-C<sub>10</sub>) heteroaryl groups];

Art Unit: 1626

 $R^5$  is: hydrogen; halo; hydroxy;  $-\text{CN}$ ; $\text{HO}-(\text{C}_1-\text{C}_6)$  alkyl  $-$ ; and $(\text{C}_1-\text{C}_6)$  alkyl,wherein the  $(\text{C}_1-\text{C}_6)$  alkyl group is optionally substituted by one to threefluoro,  $(\text{C}_1-\text{C}_6)$  alkoxy optionally substituted with one to three fluoro, $\text{HO}_2\text{C}-$ ,  $(\text{C}_1-\text{C}_6)$  alkyl- $\text{O}-(\text{C}=\text{O})-$ ,  $\text{R}^6\text{R}^8\text{N}(\text{O}_2\text{S})-$ ,  $(\text{C}_1-\text{C}_6)\text{alkyl}-(\text{O}_2\text{S})-\text{NH}-$ , $(\text{C}_1-\text{C}_6)\text{alkyl}-\text{O}_2\text{S}-[(\text{C}_1-\text{C}_6)\text{alkyl}-\text{N}]-$ ,  $\text{R}^6\text{R}^8\text{N}(\text{C}=\text{O})-$ ,  $\text{R}^6\text{R}^8\text{N}(\text{CH}_2)_m-$ ,  $(\text{C}_6-$  $\text{C}_{10})$  aryl;  $(\text{C}_6-\text{C}_{10})$  aryl- $\text{O}-$ ,  $(\text{C}_3-\text{C}_8)$  cycloalkyl, and  $(\text{C}_3-\text{C}_8)$  cycloalkyl- $\text{O}-$ ; [note: does not include  $(\text{C}_1-\text{C}_{10})$  heterocyclyl or  $(\text{C}_1-\text{C}_{10})$  heteroaryl groups]; $R^6$  is: hydrogen; $(\text{C}_1-\text{C}_6)$  alkyl; $\text{HO}-(\text{C}_2-\text{C}_6)$  alkyl; and $(\text{C}_3-\text{C}_8)$  cycloalkyl; [note: does not include formation of an additional heterocyclic ring when taken together with  $R^8$ ]; $R^7$  is: hydrogen; and $(\text{C}_1-\text{C}_6)$  alkyl optionally substituted by:one to three halogens, hydroxy,  $-\text{CN}$ ,  $(\text{C}_1-\text{C}_6)$  alkoxy $-$ ;  $(\text{C}_2-\text{C}_6)$  alkenoxy, $(\text{C}_1-\text{C}_6)$  alkyl- $(\text{SO}_2)-$ ,  $-\text{NH}_2$ ,  $((\text{C}_1-\text{C}_6)$  alkyl) $_n\text{N}-$ ,  $((\text{C}_2-\text{C}_6)$  alkenyl) $_n\text{N}-$ , $((\text{C}_2-\text{C}_6)$  alkynyl) $_n\text{N}-$ ,  $\text{NH}_2(\text{C}=\text{O})-$ ,  $(\text{C}_1-\text{C}_6)$  alkyl- $(\text{C}=\text{O})\text{N}-$ ,  $((\text{C}_1-\text{C}_6)$ alkyl) $_n\text{N}-(\text{C}=\text{O})-$ ,  $(\text{C}_2-\text{C}_6)$  alkenyl- $(\text{C}=\text{O})\text{N}-$ ,  $((\text{C}_2-\text{C}_6)$  alkenyl) $_n\text{N}-$  $(\text{C}=\text{O})-$ ,  $(\text{C}_2-\text{C}_6)$  alkynyl- $(\text{C}=\text{O})\text{N}-$ ,  $((\text{C}_2-\text{C}_6)$  alkynyl) $_n\text{N}-(\text{C}=\text{O})-$ ,  $(\text{C}_1-$

Art Unit: 1626

$C_6$ ) alkyl-(C=O)-, ( $C_2$ - $C_6$ ) alkenyl-(C=O)-, ( $C_2$ - $C_6$ ) alkynyl-(C=O)-, ( $C_3$ - $C_{10}$ ) cycloalkyl-(C=O)-, ( $C_6$ - $C_{10}$ ) aryl-(C=O), ( $C_1$ - $C_6$ ) alkyl-(C=O)O-, ( $C_2$ - $C_6$ ) alkenyl-(C=O)O-, ( $C_2$ - $C_6$ ) alkynyl-(C=O)O-, ( $C_1$ - $C_6$ ) alkyl-O(C=O)-, ( $C_2$ - $C_6$ ) alkenyl-O(C=O)-, ( $C_2$ - $C_6$ ) alkynyl-O(C=O)-, ( $C_3$ - $C_8$ ) cycloalkyl, and ( $C_6$ - $C_{10}$ ) aryl; *[note: does not include ( $C_1$ - $C_{10}$ ) heterocyclyl or ( $C_1$ - $C_{10}$ ) heteroaryl groups];*

**R<sup>8</sup>** is: hydrogen;

( $C_1$ - $C_6$ ) alkyl;

HO-( $C_2$ - $C_6$ ) alkyl; and

( $C_3$ - $C_8$ ) cycloalkyl; *[note: does not include formation of an additional heterocyclic ring when taken together with R<sup>6</sup>];*

and **R<sup>4</sup>**, **R<sup>5</sup>** and **R<sup>7</sup>** groups above may also be optionally substituted on any carbon atom by one to three halo, hydroxy, amino, -CN, ( $C_1$ - $C_6$ )alkyl, ( $C_1$ - $C_6$ )alkoxy, -CF<sub>3</sub>, CF<sub>3</sub>O-, ( $C_1$ - $C_6$ ) alkyl-NH-, [( $C_1$ - $C_6$ ) alkyl]<sub>2</sub>-N-, ( $C_1$ - $C_6$ ) alkyl-S-, ( $C_1$ - $C_6$ ) alkyl-(S=O)-, ( $C_1$ - $C_6$ )alkyl-(SO<sub>2</sub>)-, ( $C_1$ - $C_6$ ) alkyl-O-(C=O)-, formyl, ( $C_1$ - $C_6$ ) alkyl-(C=O)-, and ( $C_3$ - $C_6$ ) cycloalkyl groups;

**m** is 1 to 2; and

**n** is 0 to 2;

**Note:** The “intended use” component of **Claim 11** (“a pharmaceutical composition *for treating a IL-1 mediated disease in a mammal comprising a therapeutically effective amount of a compound according to claim 1...and a pharmaceutically acceptable carrier or diluent*”) [emphasis added] was not drawn to the elected invention and not searched at this stage of the examination.



**3)     *The fourteen individual chemical compounds claimed in Claim 10***

The fourteen individual chemical compounds recited in **Claim 10** (page 74, line 4 – page 75, line 6) were searched as described above and found to be free of the prior art of record.

**Claim Rejections - 35 USC § 103**

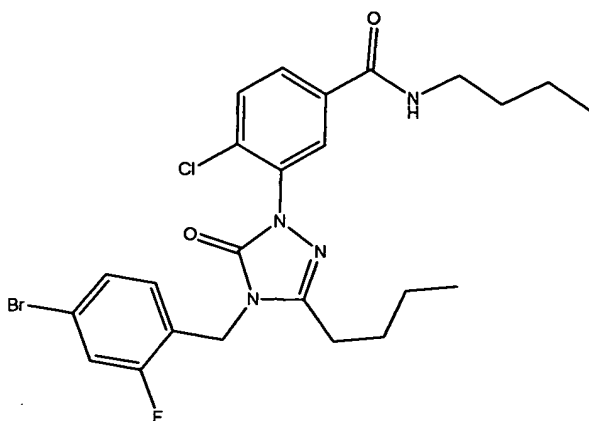
The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. §103(a) are summarized as follows:

1.     Determining the scope and contents of the prior art.
2.     Ascertaining the differences between the prior art and the claims at issue.
3.     Resolving the level of ordinary skill in the pertinent art.
4.     Considering objective evidence present in the application indicating obviousness or nonobviousness.

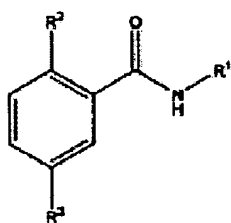
**Claims 1, 2 and 3** are rejected under 35 U.S.C. §103(a) as being unpatentable over the publication by Linda Chang, et al., which disclosed the compound 4-(4-Bromo-2-fluorobenzyl)-5-n-butyl-2-[5-(N-n-butyl-carbamoyl)-2-chlorophenyl]-2,4-dihydro-3H-1,2,4-triazol-3-one,



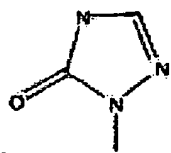
, in view of an earlier publication by the same research group (Chang, et al.) comparing chloro substituents at the “ortho,” “meta’ and “para” positions of the benzene ring for inhibitory activity in an Angiotensin II model. See Chang, L., et al., “Potent and Orally Active Angiotension II Receptor Antagonists with Equal Affinity for Human AT1 and AT2 Subtypes,” J. Med. Chem., vol. 38(19), pp. 3741-3758 (Sept. 1995), at p. 3752, lines 18 – 35 (“Chang I”); see also Chang, L., et al., “Triazolinones as Nonpeptide Angiotensin II Antagonists. 1. Synthesis and Evaluation as Potent 2,4,5-Trisubstituted Triazolinones,” J. Med. Chem., vol. 36(17), pages 2558 – 2568 (Aug. 1993), at p. 2560, col. 2, lines 14 – 36; and p. 2561, Table I, compounds 6, 10, and 14 (“Chang II”).

***Determining the scope and contents of the prior art***

**Claim 1** of the present invention discloses compounds of formula (I),



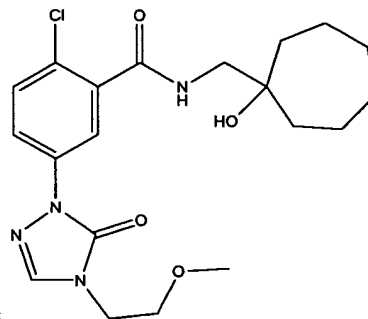
(I), where **R<sup>3</sup>** is, *inter alia*, a substituted 1,2,4-triazol-5-one group connected via



the nitrogen atom, ; **R<sup>1</sup>** is, *inter alia*, a (C<sub>1</sub>-C<sub>6</sub>) alkyl group; and **R<sup>2</sup>** is, *inter alia*, a

Art Unit: 1626

“hydrogen, halogen...” group. **Claim 2** further limits the substituents on the triazol-5-one ring ( $R^4$  and  $R^7$ ), and **Claim 3** further limits the substituent at  $R^2$  to “chloro, methyl or ethyl.” As an example, a specific embodiment of the present invention (as limited by **Claims 1, 2 and 3**) would be 2-chloro-5-[4,5-dihydro-4-(2-methoxyethyl)-5-oxo-1H-1,2,4-triazol-1-yl]-N-[(1-

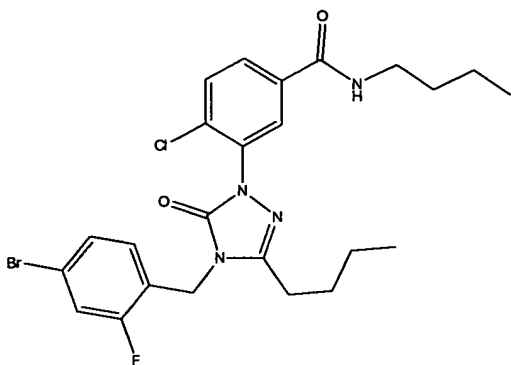


hydroxycycloheptyl)methyl] benzamido, with structure

(**Claim 10**,

example 1, page 74, lines 4 – 5). Of relevance to this analysis is that the “chloro” substituent is at the “para” position on the benzene ring relative to the triazole substituent.

The chemical compound in the prior art publication taught by Chang et al. (“Chang I”) anticipates all of the limitations of **Claims 1, 2 and 3**, except that the chloro substituent on the benzene ring is a *positional isomer* of the present genus chemical structure; i.e., the chloro substituent taught by Chang et al. is located at the “ortho” position on the benzene ring, rather than at the “para” position (as in the present invention), in relation to the triazole substituent:



Chang, et al. (Chang I), *supra*, at p. 3752, lines 18-35.

This compound was characterized as a colorless, glassy solid, with melting point 114°-116° C.

***Ascertaining the differences between the prior art and the claims at issue***

The compound taught by the prior art is a *positional isomer* of the compounds recited in the present invention; i.e., the prior art would anticipate the limitations of **Claims 1, 2 and 3** of the present invention if the chloro substituent were “para” to the triazole substituent rather than “ortho” to it. “Chang I” teaches the ortho-chloro compound, but does not teach the “para” isomer.

However, an earlier publication, “Chang II” (*supra*), had already compared the inhibitory activity of chloro substituents (and other halogens) at the “ortho,” “meta,” and “para” positions, in a rabbit model for the Angiotensin II system and taught that, among halogens, “Cl and Br were preferred to F,” and “ortho” was superior to “para,” which, in turn, was superior to “meta” for this particular model. Chang, et al. (Chang II), *supra*, a p. 2560, lines 22 – 36; and p. 2561, Table I, compounds 6, 10, and 14.

The compound in the prior art is characterized by color, appearance, melting point, and NMR peaks, but the Specification in the present application provides only the “LCMS” peaks of the fourteen compounds claimed in **Claim 10** for purposes of comparison.

***Resolving the level of ordinary skill in the pertinent art***

The compounds of the present invention would have been obvious to a person of skill in the art over the chemical compound taught by Chang, et al. (“Chang I”), 4-(4-Bromo-2-fluorobenzyl)-5-n-butyl-2-[5-(N-*n*-butyl-carbamoyl)-2-chlorophenyl]-2,4-dihydro-3H-1,2,4-triazol-3-one, in view of their prior publication in the same biological system comparing inhibitory activity for chloro substitution at the “ortho” and “para” positions (“Chang II”). Id.

Although the compounds in “Chang I” and “Chang II” were studied in rabbit models as inhibitors of “Angiotensin II (A-II) receptors,” while the compounds of the present invention are disclosed as inhibitors of “P2X<sub>7</sub> receptors,” this difference is not relevant to this analysis, as **Claims 1, 2 and 3** are for the compounds only and do not recite limitations on biological activity.

In addition, **Claims 1 and 2** of the present invention permit the substitution of a “hydrogen” atom at **R<sup>2</sup>** (Claim 1, page 70, line 11; claim 2, page 71, line 8), indicating that a “chloro” substituent at the “para” position is not necessary for the claimed activity.

A novel isomer of a known compound may be unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the known compound. See In re Norris, 84 USPQ 458, 460 – 461 (CCPA 1950). However, in this instance, the disclosure provided little physical or chemical data about the claimed compounds to compare with the data taught in the prior art by which to assess whether the properties are unobvious or unexpected.

Therefore, a person of skill in the art would have been motivated to make the claimed compounds, with a reasonable expectation of success because of the previous disclosures in “Chang I” and “Chang II,” *supra*.

Based upon the analysis above, **Claims 1, 2 and 3** are rejected under 35 U.S.C. §103(a).

**Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 6** is rejected under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, because it recites values for variable **R<sup>7</sup>** which are outside of the range of values for **R<sup>7</sup>** in two of the preceding claims from which **Claim 6** depends (**Claim 4** and **Claim 5**). **This rejection would be obviated by**

Art Unit: 1626

changing the dependency in Claim 6 from “A compound of *any of the preceding claims*” to “A compound of *any one of claims 1, 2 or 3...*” [emphasis added].

Likewise, Claim 7 is rejected under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, because it recites values for variable  $R^7$  which are outside of the range of values for  $R^7$  in three of the preceding claims from which Claim 7 depends (Claim 4, Claim 5, and Claim 6). This rejection would be obviated by changing the dependency in Claim 7 from “A compound of *any of the preceding claims*” to “A compound of *any one of claims 1, 2 or 3...*” [emphasis added].

Claim 8 is rejected under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, because it recites values for variable  $R^7$  which are outside of the range of values for  $R^7$  in four of the preceding claims from which Claim 8 depends (Claim 4 – 7). This rejection would be obviated by changing the dependency in Claim 8 from “A compound of *any of the preceding claims*” to “A compound of *any one of claims 1, 2 or 3...*” [emphasis added].

Claim 9 is rejected under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, because it recites values for variable  $R^7$  which are outside of the range of values for  $R^7$  in five of the preceding claims from which Claim 9 depends (Claims 4 – 8). This rejection would be obviated by changing the dependency in Claim 9 from “A compound of *any of the preceding claims*” to “A compound of *any one of claims 1, 2 or 3...*” [emphasis added].

### **Claim Objections**

Claims 3, 4, 5, 6, 7, 8, 9 and 11 are objected to as being dependent upon a rejected base claim. See MPEP §608.01(n)(V).

Claims 1 and 2 are also objected to for the following claim informalities: As to Claim 1, on page 70, lines 7, 12 and 16, the terms “*suitable* moieties” and “*suitably* substituted” [emphasis

Art Unit: 1626

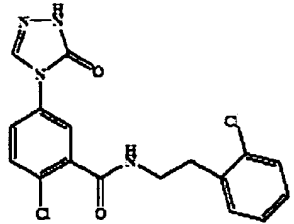
added] render the scope of the claim unclear. Interpreted in light of the definition provided in the Specification, a “suitable substituent” is an open-ended list (“illustrative examples include, but are not limited to halo groups, perfluoroalkyl groups...aryl or heteroaryl groups...” etc.), that is limited only by language that the “suitable substituent” must be “a moiety that does not negate the biological activity of the inventive compounds” (Specification at page 5, line 20 – page 6, line 2). It is not clear from the claim, even when read in view of the Specification, whether “hydrogen,” for instance, would be included as a “suitable substituent.” The same rationale applies to the multiple uses of “suitable” in **Claim 2**, at page 71, lines 4, 9, 16, and 23; and page 72 at line 4. **A suggestion to clarify the claim language would be to delete the words “suitable” and “suitably” from Claims 1 and 2 in each place it occurs.**

**Claim 1** is also objected to for the following claim informalities: on page 70, line 8, the bond showing the attachment of the cyano group (CN) appears to be on the incorrect side to indicate bonding via the carbon atom.

**Claim 2** is also objected to because the phrase “such as” is unclear in its scope. See MPEP § 2173.05(d). For example, **Claim 2** recites, “...wherein R<sup>4</sup> and R<sup>5</sup> are independently selected from the group of suitable substituents, *such as* hydrogen, halo, hydroxy...” [emphasis added]). **Claim 2** at page 71, lines 17 and 23. While the use of the phrase “such as” in a claim does not always render the claim unclear, in these several instances it is uncertain whether “such as” is intended simply to provide examples of a closed set of variables, or, in fact, converts the group to an open-ended set. **A suggestion to obviate this objection is to replace the phrase “such as” in both places it appears (Claim 2, page 71, lines 17, 23) with the phrase “consisting of.”**

**Note on co-pending application**

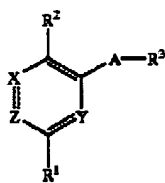
**Co-pending U.S. Application No. 10/292,887** (published as **US 2003/0186981 A1** on October 2, 2003; filing date Nov. 12, 2002), disclosed the compound 2-chloro-N-[2-(2-chloro-

phenyl)ethyl-5-(5-oxo-1,5-dihydro-[1,2,4]triazol-4-yl) benzamido,  (See

US 2003/0186981, "Example 58," at p. 45, col. 1, lines 4 – 19 and col. 2, lines 21 – 24), which appears to meet the limitations for **Claims 1 – 3** of the present invention; however, this reference does not read on the compounds of the present invention because the triazole ring is attached to the benzene ring *via a different nitrogen atom*.

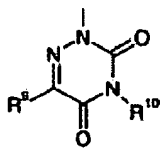
Of note for this reference, too, is that the original claims for **co-pending U.S.**

**Application No. 10/292,887** appear to read on the present invention ("...a compound of formula



, where 'A is  $-(C=O)NH-$ , 'X, Y and Z are  $=(CR^6)-$ ,  $=(CR^7)-$ , and  $=(CR^8)-$ , and

'R<sup>1</sup> is a nitrogen-linked (C<sub>1</sub>-C<sub>10</sub>) heterocyclyl containing one to six heteroatoms..." see **Claim 1** at p. 80, lines 1 – 15 of the original disclosure); however, the claims were amended prior to the Notice of Allowability, mailed on February 9, 2005, such that **R<sup>1</sup>** was limited to the 3,5-dioxo



triazinyl group, thereby avoiding a potential double patenting rejection in the present application.



Art Unit: 1626

**Conclusion**

**Claims 1, 2 and 3** are rejected pursuant to 35 U.S.C. §103(a).

**Claims 6, 7, 8 and 9** are rejected pursuant to 35 U.S.C. §112, 2<sup>nd</sup> paragraph.

**Claims 3 – 9 and 11** are objected to as depending upon a rejected base claim.

**Claims 1 and 2** are objected to for claim informalities.

**Claim 10** appears to be free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Anthony J. Paviglianiti** whose telephone number is **(571) 272-3107**. The examiner can normally be reached on Monday-Friday, 8:30 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached at (571) 272-0699. **The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Please note that this is a new central FAX number for all official correspondence.**

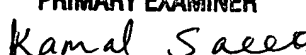
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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